IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

THE STATE OF LOUISIANA,
By and through its Attorney General, JEFF LANDRY;

THE STATE OF MONTANA,
By and through its Attorney General, AUSTIN KNUDSEN;

THE STATE OF ARIZONA,
By and through its Attorney General, Mark Brnovich;

THE STATE OF ALABAMA, By and through its Attorney General, STEVE MARSHALL;

THE STATE OF GEORGIA, By and through its Attorney General, CHRISTOPHER CARR;

THE STATE OF IDAHO, By and through its Attorney General, LAWRENCE G. WASDEN;

THE STATE OF INDIANA, By and through its Attorney General, THEODORE M. ROKITA;

THE STATE OF MISSISSIPPI, By and through its Attorney General, LYNN FITCH;

THE STATE OF OKLAHOMA, By and through its Attorney General, JOHN M. O'CONNOR;

THE STATE OF SOUTH CAROLINA, By and through its Attorney General, ALAN WILSON;

THE STATE OF UTAH, By and through its Attorney General, SEAN D. REYES;

THE STATE OF WEST VIRGINIA, By and through its Attorney General, PATRICK MORRISEY;

CIVIL ACTION NO. _____

PLAINTIFFS,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; et al.,

DEFENDANTS.

MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

The Biden Administration is playing statutory shell games with the courts, straining to justify an unjustifiable and unprecedented attempt to federalize public health policy and diminish the sovereign States' constitutional powers. The Administration has announced three COVID-19 vaccine mandates to—as the President himself has confirmed—increase societal vaccination rates. There's just one problem: no statute authorizes the federal Executive to mandate vaccines to increase societal immunity. The Administration's solution? Use statutory schemes never before interpreted to allow federal vaccine mandates to shoehorn the President's goals into the fabric of American society. In one instance, the Administration grabbed an obscure workplace safety statute to impose a vaccine mandate on 100 million Americans. That mandate suffers from so many patent constitutional and statutory problems that the Fifth Circuit stayed it a day after it issued and reaffirmed its stay within a week. *BST Holdings, L.L.C. v. OSHA*, No. 21-60845 (Nov. 12, 2021). Second, the Administration tried to use the federal procurement system to impose a vaccine mandate on another fifth of the American workforce. That mandate, too, is already subject to multiple legal challenges. The third mandate is the one at issue here: the Administration has coopted the Medicare and Medicaid system to impose a vaccine on 17 million healthcare workers.

But the Social Security Act focuses on *patient* welfare and *patient* access to care. By forcing a significant number of healthcare workers to take the vaccine or exit the Medicare and Medicaid workforce, CMS's Vaccine Mandate harms access to (and thus quality of) patient care. This "one-size-fits-all sledgehammer" expressly undermines the Social Security Act's singular focus on providing access to care. *BST Holdings,* No. 21-60845, slip op. at 6 (5th Cir. Nov. 12, 2021). By forcing healthcare workers to choose "between their job(s) and their jab(s)," *id.* at 19, the Mandate completely ignores the unprecedented labor shortage prevailing in the healthcare sector and patient wellbeing in favor of the President's policy of increasing societal vaccination rates.

The President's attempt to use the Social Security Act to endanger patient welfare must be stopped. Aside from being fundamentally at odds with the Social Security Act, the Vaccine Mandate suffers from a host of fatal flaws. It exceeds CMS's statutory authority; violates the Social Security Act's prohibition on regulations that control the selection and tenure of healthcare workers; is arbitrary and capricious; and violates the Spending Clause, the Anti-Commandeering doctrine, and the Tenth Amendment. Furthermore, CMS flouted the basic procedural requirements that Congress imposed on it, including the Administrative Procedure Act's notice-and-comment requirement, the Congressional Review Act's publication-and-review requirements, and the Social Security Act's consultation and regulatory-impact-analysis requirements. The Vaccine Mandate will gravely harm the vulnerable persons whom Medicare and Medicaid were designed to protect—the poor, sick, and elderly—by forcing the termination of millions of essential "healthcare heroes."

BACKGROUND

I. THE MEDICARE AND MEDICAID FRAMEWORK ESTABLISHED BY CONGRESS.

Since 1965, the federal government and the States have worked together to provide medical assistance to certain vulnerable populations under Titles XVIII and XIX of the Social Security Act, commonly known as Medicare and Medicaid. *See* 42 U.S.C. §§1395-1396 *et seq.* Medicare is a federal program that pays for healthcare for the elderly; Medicaid is a cooperative state-federal program that helps States finance medical care for their poor and disabled citizens. The Social Security Act charges the Secretary of Health and Human Services with a wide range of administrative responsibilities related to maintaining the Medicare and Medicaid programs. *See* 42 U.S.C. §301 *et seq.* It also delegates to the Secretary certain limited rulemaking authority, including—as most relevant here—the authority to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged under this chapter." 42 U.S.C. §1302(a). The Centers for Medicare & Medicaid Services, a federal agency within the

Department of Health and Human Services, has primary responsibility for overseeing Medicare and Medicaid programs. But Medicaid is a federal-state cooperative program, and States play an essential role in administering it and ensuring compliance with CMS rules.

II. THE BIDEN ADMINISTRATION'S VACCINE POLICY.

As President-Elect, Mr. Biden said he "d[i]dn't think [vaccines] should be mandatory" and "wouldn't demand [they] be mandatory." Jacob Jarvis, *Fact Check: Did Joe Biden Reject Idea of Mandatory Vaccines in December 2020*, Newsweek (Sept. 10, 2021), https://bit.ly/3ndyTn5. Until recently, his Administration followed suit. *See, e.g.*, Press Briefing by Press Secretary Jen Psaki, July 23, 2021, https://bit.ly/3pWnJVr (mandating vaccines "not the role of the federal government").

But as time passed, the President admitted that his "patience" began "wearing thin" with those "who haven't gotten vaccinated." The White House, Remarks by President Biden on Fighting the COVID-19 Pandemic (Sept. 9, 2021), https://bit.ly/3Ey4Zj6. So in early September 2021, the Administration abandoned persuasion for brute force and announced a series of unprecedented federal mandates aimed at compelling most of the adult population of the United States to get a COVID-19 vaccine. *Id.* His goal? To "increase vaccinations among the unvaccinated with new vaccination requirements." *Id.*; *see also* The White House, Path Out of the Pandemic: President Biden's Covid-19 Action Plan, https://bit.ly/3adkMXx; The White House, Vaccination Requirements Are Helping Vaccinate More People, Protect Americans from COVID-19, and Strengthen the Economy (Oct. 7, 2021), https://bit.ly/3lorbp0.

In part, those vaccine requirements include the actions challenged here. President Biden announced he would impose—though unilateral executive action—a vaccine mandate on "a total of 17 million workers." Biden Sept. 9, 2021 Remarks, *supra*. As he explained, he'd already announced his intent to "requir[e] vaccinations that [sic] all nursing home workers who treat patients and Medicare and Medicaid," contending that he "ha[s] that federal authority." *Id.* Now, invoking "that same"

purported "authority," he "expand[ed] that" edict "to cover those who work in hospitals, home healthcare facilities, or other medical facilities." *Id.* No contrary State law would stand in his way: If any "governor[s]" opposed the new federal mandates, he promised to "use [his] power as President to get them out of the way." *Id.*

III. THE CMS VACCINE MANDATE.

On November 5, 2021, CMS published an interim final rule requiring vaccination of staff by 21 types of Medicare and Medicaid providers subject to Medicare or Medicaid conditions of participation, conditions for coverage, or requirements for participation. Medicare and Medicaid Programs; Omnibus COVID-19 Heath Care Staff Vaccinations, 86 Fed. Reg. 61555, 61556 (Nov. 5, 2021) ("the IFC" or "the Vaccine Mandate"). The rule applies the same substantive standards to each of the 21 types of entities. *See id.* at 61570, 61616-61627. As CMS put it, "we are issuing a common set of provisions for each applicable provider and supplier." *Id.* at 61570. There are "no substantive regulatory differences across settings." *Id.*

The regulations themselves require that every type of covered entity "develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19." *See, e.g.*, 42 C.F.R. §416.51(c). The policy must apply to every person "who provide[s] any care, treatment, or other services for the [entity] and/or its patients," including employees, contractors, trainees, students, and volunteers. *Id.* §416.51(c)(1). To be exempted from the policy, a healthcare worker must "exclusively provide" telehealth or support services "outside of the [entity's] setting" and "not have any direct contact with patients and other staff." *Id.* §416.51(c)(2). The entity must ensure that, by December 6, 2021, all such healthcare workers submit to at least one vaccine dose before they can provide "any care, treatment, or other services for the [entity] and/or its patients." *Id.* §416.51(c)(3)(i); 86 Fed. Reg. at 61555. The entity must then ensure that, by January 4, 2022, all such healthcare workers "are fully vaccinated." 42 C.F.R. §416.51(c)(3)(ii); 86 Fed. Reg. at 61555.

Additionally, the entity may exempt those granted temporary delays based on the CDC's recommendations or those who are eligible for exemptions under certain federal statutes. 42 C.F.R. §416.51(c)(3). But the entity must "track[] and securely document[] information provided by those staff who have requested, and for whom the [entity] has granted, an exemption" or a temporary delay. *Id.* §416.51(c)(3)(vi)-(vii). And it must ensure that all documentation "support[ing] staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner" with specific information about which vaccines are clinically contraindicated and a statement of reasons for each. *Id.* §416.51(c)(3)(viii). The entity must also implement a "process for tracking and securely documenting the COVID–19 vaccination status of all staff," including their booster-shot status. *Id.* §416.51(c)(3)(iv)-(v). Finally, the entity must implement "[c]ontingency plans" for all persons who are "not fully vaccinated." *Id.* §416.51(c)(3)(x). The regulations further mandate "that all staff COVID-19 vaccines must be appropriately documented by the provider or supplier," and provide that "[e]xamples of acceptable forms of proof of vaccination include: ... State immunization information system record." 86 Fed. Reg. at 61572.

The only way for an entity to avoid those regulations is to forfeit its federal funding. And an entity that fails to comply fully with the regulations may face penalties up to and including "termination of the Medicare/Medicaid provider agreement," 86 Fed. Reg. at 61574—a death knell for most every provider. This is the first—and only—mandatory vaccination program in the history of the Medicare or Medicaid programs. *See id.* at 61567 ("We have not previously required any vaccinations."); *id.* at 61568 ("We acknowledge that we have not previously imposed such requirements.").

IV. IMPLICATIONS FOR HEALTHCARE WORKERS AND VULNERABLE AMERICANS.

According to CMS, the Vaccine Mandate regulates over 10.3 million health care workers in the United States. *Id.* at 61603. Of those, CMS estimates that roughly 2.4 million are currently unvaccinated. *Id.* at 61607. Those healthcare workers are the Vaccine Mandate's targets. CMS's

objective is to coerce them into submission or cause them to lose their livelihoods. *See id.* at 61607 ("The most important inducement will be the fear of job loss, coupled with the examples set by fellow vaccine-hesitant workers who are accepting vaccination more or less simultaneously"); *id.* at 61608 ("it is possible there may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients"). Though narrow medical and religious exemptions may be granted, the program's goal is plain: vaccinate "nearly all health care workers." *Id.* at 61569.

This Mandate, however, portends catastrophic consequences for Medicaid beneficiaries' access to healthcare. Because workers in the healthcare industry have already faced prolonged pressure to undergo vaccination, and because many others have not submitted to employer-imposed mandates, it stands to reason that many of the 2.4 million unvaccinated healthcare workers the Mandate targets will not submit to vaccination. If the Vaccine Mandate is not enjoined, these healthcare workers will lose their jobs. When that happens, America's most vulnerable populations will lose access to necessary medical care. CMS acknowledges that there are currently "endemic staff shortages for all categories of employees at almost all kinds of health care providers and suppliers." *Id.* at 61607. And of course, it acknowledges that "these may be made worse" when unvaccinated workers leave as a result of the rule. *Id.*

A few statistics illustrate the extent of the problem. Already 39% of nursing homes in Montana face staff shortages. *See* AARP Nursing Home COVID-19 Dashboard, AARP Public Policy Institute (Nov. 10, 2021), bit.ly/30lrvgs. That number exceeds 45% in Georgia, Idaho, and Utah, and ranges from 11% to 43% in the remaining Plaintiff States. Meanwhile, somewhere between 22% and 42% of healthcare workers in those states are not fully vaccinated, despite having faced considerable pressure to get vaccinated. *Id.* CMS admits that it does not know how many unvaccinated workers will submit. *Id.* at 61607, 61612. It brushes aside the specter of chronic healthcare shortages with bureaucratic

jargon, suggesting that "while it is true that compliance with this rule may create some short-term disruption of current staffing levels for some providers or suppliers in some places, there is no reason to think that this will be a net minus even in the short term, given the magnitude of normal turnover and the relatively small fraction of that turnover that will be due to vaccination mandates." *Id.* at 61609.

ARGUMENT

To obtain a preliminary injunction, Plaintiff States "must show: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable harm if the injunction is not granted; (3) that the threatened injury outweighs any harm that the injunction might cause to the defendant; and (4) that the injunction will not disserve the public interest." *Opulent Life Church v. City of Holly Springs, Miss.*, 697 F.3d 279, 288 (5th Cir. 2012). Each factor weighs in the Plaintiff States' favor.

I. PLAINTIFF STATES ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS.

The Vaccine Mandate suffers from a panoply of fatal procedural and substantive flaws. Each suffices to justify enjoining it.

A. Defendants Issued the Vaccine Mandate Without Following Statutorily Required Processes.

Consider first the Vaccine Mandate's obvious procedural flaws. The Administrative Procedure Act requires agencies to publish notice of all "proposed rule making" in the Federal Register, *id.* §553(b), and to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* §553(c). Likewise, the Social Security Act requires the HHS Secretary, before issuing the relevant types of regulations "in final form," to "provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. §1395hh(b)(1).

CMS does not dispute that the IFC is subject to those notice-and-comment requirements—and that CMS failed to comply with them. 86 Fed. Reg. at 61583. Instead, CMS's sole reason for not conducting notice and comment is the APA's "good cause" exception, which allows agencies to

dispense with notice-and-comment procedures only "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §553(b)(B); *see id.* §553(d)(3); 42 U.S.C. §§1395hh(b)(2)(C) and (e)(1)(B)(ii). CMS claims that this case presents that kind of emergency "as a result of the COVID-19 public health emergency." 86 Fed. Reg. at 61555. CMS concludes that "[i]n light of [its] responsibility to protect the health and safety of individuals providing and receiving care and services from Medicare-and Medicaid-certified providers and suppliers," CMS is "compelled to require staff vaccinations for COVID-19 in these settings" without required notice and comment. *Id.* at 61560; *see also id.* at 61583-61586 (notice and comment "impracticable" because of "a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to patients from unvaccinated health-care workers, and continuing strain on the health care system and known efficacy and safety of available vaccines").

CMS's view contravenes "well established" precedent that "the 'good cause' exception to notice-and-comment should be read narrowly in order to avoid providing agencies with an 'escape clause' from the requirements Congress prescribed." *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011). "[C]ircumstances justifying reliance on this exception are 'indeed rare' and will be accepted only after the court has 'examine[d] closely proffered rationales justifying the elimination of public procedures.'" *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 473, 580 (D.C. Cir. 1981) (citation omitted). Courts therefore restrict agencies' use of the "good cause" exception "to emergency situations," *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 93 (D.C. Cir. 2012) (citation omitted), such as where a "delay would imminently threaten life or physical property" or risk "fiscal calamity," *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706-07 (D.C. Cir. 2014).

CMS's good-cause explanation falls far below those exacting standards. In claiming that it must immediately implement the Vaccine Mandate, CMS ignored that it waited almost two months after President Biden's directive before promulgating the IFC. *Cf. BST Holdings*, No. 21-60845, at 7 (staying OSHA ETS mandate and noting same two-month delay). Beyond that, CMS's finding that the Vaccine Mandate is necessary was undermined by that same delay. *See id.* at 7 n.11 ("One could query how an 'emergency' could prompt such a 'deliberate' response."). Vaccines have had a Food & Drug Administration Emergency Use Authorization for almost a year (as CMS knows, *see* 86 Fed. Reg. at 61584), yet CMS did not impose this Mandate until two months after the President instructed it to do so as part of his "six-point plan" to federalize public-health policy. Here, no "emergency" sufficient to justify CMS's dispensing with proper rulemaking exists. *BST Holdings*, No. 21-60845, at 7 ("The Mandate's stated impetus—a purported 'emergency' that the entire globe has now endured for nearly two years, and which OSHA itself spent nearly two months responding to—is unavailing as well."); *Florida v. Becerra*, 2021 WL 2514138, at *45 (M.D. Fla. June 18, 2021) (concluding that the COVID-19 pandemic was insufficient for "good cause"); *Regeneron Pharms. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020) (similar).[1]

By all measures, COVID-19 infection rates, hospitalizations, and fatalities have declined from other, earlier times when the Administration declined to act. *See, e.g.*, Joshua R. Miller, *Los Angeles County sheriff blasts vaccine mandate causing 'mass exodus,'* N.Y. Post (Oct. 29, 2021), https://bit.ly/3n5I9tm. And the pandemic is a feeble excuse for avoiding transparency and public input considering the year-long public debate over mandatory vaccines. *See BST Holdings*, No. 21-60845, at 7 n.10 ("'[I]f human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency.'"); *see also Chamber of Commerce of the U.S. v. DHS*, 2020 WL 7043877, at

[1] Given the IFC's impact on State interests, failure to conduct notice and comment was not harmless. *See Johnson*, 632 F.3d at 931.

*8 (N.D. Cal. Dec. 1, 2020); *see also Ass'n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d 482, 496 (D. Md. 2020) ("CMS here relies more on speculation than on evidence to establish that the COVID-19 pandemic has created an emergency in Medicare Part B drug pricing sufficient to justify dispensing with valuable notice and comment procedures."). For the same reasons, CMS's reliance on the good-cause exception to avoid the Congressional Review Act's procedures was unlawful. *See* 5 U.S.C. §808.

B. The Vaccine Mandate Is Beyond the Executive's Authority and Contrary to Law.

1. The Vaccine Mandate Is Beyond the Executive's Authority.

The Vaccine Mandate also must be enjoined because it exceeds the Executive's statutory authority. The Supreme Court "expect[s] Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014). Nor can the Executive "bring about an enormous and transformative expansion in [its] regulatory authority without clear congressional authorization." *Id.*; *see also Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000) (rejecting Executive claim to "jurisdiction to regulate an industry constituting a significant portion of the American economy" absent clear congressional authorization); *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001) (Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions").

Defendants, however, identify no clear statutory authority authorizing the Vaccine Mandate. The Fifth Circuit has already confirmed this fatal flaw in the Biden Administration's parallel and similar attempt to mandate vaccinations for employees of 100-person companies. *BST Holdings v. OSHA*, No. 21-60845, slip op. at 6 (5th Cir. Nov. 12, 2021). That conclusion is no surprise given the lack of precedent for OSHA's mandate; likewise, never in CMS's history has it relied upon its Social Security Act authority to mandate healthcare worker vaccination. *See, e.g.*, 86 Fed. Reg. at 61567. Indeed, it is hard to recall any time in American history when any federal entity has claimed the power to force

millions of Americans to inject themselves with something against their wills. *Cf. NFIB. v. Sebelius*, 567 U.S. 519, 608 (2012) (Ginsburg, J., dissenting in relevant part) (disavowing "implication that Congress may justify under the Commerce Clause a mandate to buy other products and services"). The Court should view CMS's attempt to do so now with heightened caution. "[T]here is a first time for everything," but "sometimes 'the most telling indication of [a] severe constitutional problem ... is the lack of historical precedent.'" *NFIB*, 567 U.S. at 549.

In any event, CMS's first Vaccine Mandate fails under the SSA's plain terms. Its conferrals of general rulemaking authority do not contain a clear statement authorizing the Vaccine Mandate. CMS relies principally upon Section 1102 and Section 1871, but those are mere general authorizations to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs," 42 U.S.C. §1395hh(a)(1), and to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration" of the Medicare program, 42 U.S.C. §1302(a). Nothing in those grants of general rulemaking authority clearly authorizes an action with the vast economic and political significance of a national vaccine mandate.

Implicitly acknowledging that failing, CMS also cites 15 separate statutes to try to justify applying the Vaccine Mandate to specific types of facilities. 86 Fed. Reg. at 61567; *see* Doc. 1. ¶¶ 47-66. Not one of those statutes, however, expressly authorizes CMS to impose a vaccine mandate. Instead, they grant mine-run authority to govern unexceptional day-to-day aspects of certain healthcare facilities: for example, to specify "standards" for "active treatment" of "inpatient psychiatric hospital services for individuals under age 21," 42 U.S.C. §1396d(h)(1)(B)(i); or "standards" for "provid[ing] health or rehabilitative services for [intellectually disabled] individuals" at Intermediate Care Facilities, *id.* §1396d(d)(1); or "health, safety, and other standards" at Ambulatory Surgical Centers, *id.* §1395k(a)(2)(F)(i); or standards for "the health and safety of individuals enrolled" in Programs of All-Inclusive Care for the Elderly, *id.* §§1395eee(f), 1396u–4(f), or Rural Health Clinics,

id. §1395x(aa)(2)(K), or Hospitals, *id.* §1395x(e)(9), or Hospices, *id.* §1395x(dd)(2)(G). Even passing scrutiny of each of those cited secondary authorities readily confirms that those Social Security Act provisions are "a wafer-thin reed on which to rest such sweeping power." *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021). That's hardly sufficient given the serious constitutional issues that the Vaccine Mandate raises. *Cf. BST Holdings, L.L.C. v. OSHA*, No. 21-60845, 2021 WL 5166656, at *1 (5th Cir. Nov. 6, 2021) (OSHA ETS raises "grave statutory and constitutional issues"). In fact, given the Mandate's subject matter, it triggers three separate clear statement rules—and fails all three.

First, Congress will "not be deemed to have significantly changed the federal-state balance" unless it "conveys its purpose clearly." *United States v. Bass*, 404 U.S. 336, 349 (1971); *see also Boelens v. Redman Homes, Inc.*, 748 F.2d 1058, 1067 (5th Cir. 1984) ("Absent a clear statement of intention from Congress, there is a presumption against a statutory construction that would significantly affect the federal-state balance."). The Mandate changes the federalism balance by intruding upon the States' police power over public health,[2] *BST Holdings*, No. 21-60845, at 16-17 ("[T]o mandate that a person receive a vaccine or undergo testing falls squarely within the States' police power."), and commandeering States to enforce a federal policy, *NFIB*, 567 U.S. at 577. Accordingly, the Act must authorize the Mandate unambiguously or not at all. *See Bond v. United States*, 572 U.S. 844, 857-58

[2] Since the Founding, pandemic response—particularly mandatory inoculation methods—has been a State and local issue. *See State v. Becerra*, 2021 WL 2514138 at *15 (M.D. Fla. June 18, 2021) ("The history shows ... that the public health power ... was traditionally understood—and still is understood—as a function of state police power."); *see also id.* at *11 (citing CDC, History of Quarantine (Feb. 12, 2007)) ("In the early years of the republic, the federal role in curbing infectious disease extended to little more than support for the effort of local government."). To the extent Congress has tried to address vaccination and pandemic control through mandatory federal means, it has been through authorities granted to the Centers for Disease Control and Prevention or the Food and Drug Administration rather than through the Social Security Act. *See, e.g.*, 42 U.S.C. §264; 21 U.S.C. §360bbb-3. But even there, federal courts have twice checked CDC for overreaching on COVID-19. *See Ala. Ass'n of Realtors*, 141 S. Ct. at 2486-90; *Becerra*, 2021 WL 2514138 at *15.

(2014) ("'[I]t is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides' the 'usual constitutional balance of federal and state powers.'"). It's the latter.

Second, because the Executive cannot unilaterally "push the limit of congressional authority," courts require a clear statement before adopting an Executive interpretation that would raise serious constitutional issues. *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Engr's*, 531 U.S. 159, 172-73 (2001). Besides raising serious Spending Clause and Tenth Amendment problems, *see infra* Sec. I.D, the Vaccine Mandate raises grave constitutional questions under the Nondelegation Doctrine. If Defendants are right that the Social Security Act grants authority for federal vaccine mandates, both "the degree of agency discretion" and "the scope of the power congressionally conferred" by the Act would be limitless. *Id.* at 475. Congress, however, lacks authority to delegate "unfettered power" over the American economy to an executive agency.[3] *Tiger Lily, LLC v. HHS*, 5 F.4th 666, 672 (6th Cir. 2021); *see also BST Holdings*, No. 21-60845, at 6; *Florida v. Becerra*, 2021 WL 2514138, at *20, *37. Accordingly, Congress's purported "delegation ... of authority" in the SSA "to decide major policy questions"—such as whether all healthcare workers must be vaccinated—would violate the nondelegation doctrine. *Paul v. United States*, 140 S. Ct. 342 (2019) (statement of Justice Kavanaugh respecting the denial of certiorari); *see also Tiger Lily*, 5 F.4th at 672 ("[T]o put 'extra icing on a cake already frosted,' the government's interpretation of § 264(a) could raise a nondelegation problem."); *State v. Becerra*, 2021 WL 2514138, at *37.

Third, Congress must clearly delegate power to the Executive to address issues of "deep economic and political significance." *King v. Burwell*, 576 U.S. 473, 486 (2015). If vaccine mandates are not of deep economic and political significance, it's hard to imagine what is. The Vaccine Mandate affects hundreds of billions of dollars in federal funds and grants. And "[d]ebates over the Biden

[3] To see where such unfettered power can lead, see Reuters, *Austria orders non-vaccinated people into COVID-19 lockdown* (Nov. 14, 2021), https://tmsnrt.rs/3Hln1HL.

Administration's forthcoming vaccine mandate roiled the country throughout much of the Fall." *BST Holdings*, No. 21-60845, at 3 n.4. Accordingly, "the sheer scope of [Defendants'] claimed authority under [the Act] counsel[s] against the Government's interpretation." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489; *BST Holdings*, No. 21-60845, at 17-18 ("The Mandate derives its authority from an old statute employed in a novel manner, imposes nearly $3 billion in compliance costs, involves broad medical considerations that lie outside of OSHA's core competencies, and purports to definitively resolve one of today's most hotly debated political issues.").

The statutory authority cited by CMS simply does not run this gauntlet of clear statement rules. If Congress wishes to alter federal-state relations; press its Article I powers; and regulate an area of immense political, social, and economic importance, it must do so clearly. "It is up to Congress," not Defendants, "to decide whether the public interest merits further action here." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489; *cf. BST Holdings*, No. 21-60845, at 18 ("There is no clear expression of congressional intent in §655(c) to convey OSHA such broad authority, and this court will not infer one. Nor can the Article II executive breathe new power into OSHA's authority—no matter how thin patience wears.").

2. The Vaccine Mandate Is Contrary to Law.

The Vaccine Mandate violates several discrete sections of the Social Security Act. *First*, under 42 U.S.C. §1395z, "the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies," when "carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and[] (dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) of this title." CMS acknowledges that this consultation requirement applies to the Vaccine Mandate—and concedes that it did not comply with it. 86 Fed. Reg. at 61567. CMS's "inten[t] to engage in consultations with appropriate State agencies ... following the issuance of th[e] rule," 86 Fed. Reg. at 61567, is no adequate substitute;

the statute plainly requires consultation with States *before* a rule is issued whenever the Secretary is "carrying out his functions[] relating to determination of conditions of participation by providers of services." 42 U.S.C. §1395z.

Second, 42 U.S.C. §1395 provides that nothing in Title 18 of the Social Security Act "shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person." The Vaccine Mandate violates 42 U.S.C. §1395 by purporting to authorize federal officials at CMS to exercise "supervision" and "control" over the "selection" and "tenure" of employees (including state employees) and other persons "providing health services." It does so by prohibiting covered healthcare facilities from hiring unvaccinated employees and forcing those facilities to terminate—and thus end the tenure of—unvaccinated employees. The Vaccine Mandate also violates §1395 because it authorizes federal officials at CMS to exercise "supervision" and "control" over the "administration" and "operation" of institutions, agencies, and persons that provide health services (including state facilities and employees) by dictating the hiring and firing policies of those institutions for unvaccinated workers.

Third, 42 U.S.C. §1302(b)(1) requires that "[w]henever the Secretary [of HHS] publishes a general notice of proposed rulemaking for any rule or regulation proposed under subchapter XVIII, subchapter XIX, or part B of [title IX of the Social Security Act] that may have a significant impact on the operations of a substantial number of small rural hospitals, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis." 42 U.S.C. §1302(b)(1) applies because the Mandate will have a significant impact on the operations of a substantial number of small rural hospitals. The CMS Vaccine Mandate threatens to exacerbate already devastating shortages in

healthcare staffing by forcing small rural hospitals to terminate their unvaccinated workers. That, in turn, will compel those hospitals to close certain divisions, cancel certain services, or shutter altogether. Those dire consequences stretch across rural America, and their collective force required CMS to prepare a regulatory impact analysis. It refused to do so.

C. The Vaccine Mandate Is Arbitrary and Capricious.

The APA commands courts to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion." 5 U.S.C. §706(2)(A). To clear that hurdle, federal administrative agencies must "engage in 'reasoned decisionmaking.'" *Texas v. United States*, 2021 WL 723856, at *39. The Vaccine Mandate is arbitrary and capricious for several independently sufficient reasons.

First, the IFC ignores the Social Security Act's focus on patient wellbeing rather than the health of providers. Each prong of the President's vaccination policy is aimed at the same overarching goal: increasing individual vaccination rates. *See* Remarks by President Biden on Fighting the COVID-19 Pandemic" (Sept. 9, 2021), https://bit.ly/3oI0pKr (CMS Vaccine Mandate part of President's plan to "increase vaccinations among the unvaccinated with new vaccination requirements"). But the evidence, even that relied upon by CMS, shows that mandating vaccines will harm patient health and wellbeing. For example, the Mandate will cause nursing home staff shortages that will significantly harm patient health and well-being. There is already a critical shortage of healthcare workers. In Montana alone, there is already a 39% nurse and aide shortage in nursing homes. AARP, "AARP Nursing Home COVID-19 Dashboard" (updated Nov. 10, 2021), https://bit.ly/3HhAWyy. And studies show that Vaccine Mandates will exacerbate those shortages. *See* Liz Hamel, et al., *KFF COVID-19 Vaccine Monitor: Oct, 2021*, Kaiser Family Foundation (Oct. 28, 2021), https://bit.ly/3wEiJWN; Chris Isidore & Virginia Langmaid, *72% of unvaccinated workers vow to quit if ordered to get vaccinated*, CNN.com (Oct. 28, 2021), https://cnn.it/3HdgDlw. Those outcomes do "not

rest on mere speculation about the decisions of third parties" but instead on "the predictable effect of Government action on the decisions of third parties," meaning CMS *a fortiori* knows the Mandate's deleterious effects on the parties it wants to regulate. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019).

Consider just a few real-world examples from Plaintiff States—which notice-and-comment rulemaking would have disclosed to CMS, had the agency deigned to conduct it. As one Hospital Director put it, "I fear that our rural hospital will soon face closing the doors permanently" because of the Mandate. Ex. F ¶5; *see also* Ex. K ¶7 ("While the percentage of over-all employees that the hospital will lose because of the mandate may not be significant, because we have very small departments and employee specialties are not interchangeable, losing even 10 or 20 employees, which is a likely outcome of the mandate, may have devastating results to our ability to provide the level of care we have provided in the past."). The owner of a skilled nursing facility in Pollock, Louisiana, that employs 56 staff members verifies "that approximately 43% of [its] employees are not vaccinated with the coronavirus vaccine"; that "most, if not all," of those employees will "either be unwilling or unable to take the vaccine against coronavirus as mandated by CMS"; and that if it "lose[s] 43% of our workforce, [it] will be unable to provide safe and efficient care to our residents," raising the specter that "our rural nursing facility will soon face closing the doors permanently." Ex. A ¶¶4-5; *see also Rural COVID patients in ICUs at higher risk of dying than urban counterparts, according to WVU researcher*, WVU Today (Nov. 11, 2021), https://bit.ly/3HnFB1Q. Similarly, the CEO of two rural hospitals in Utah reports that the Mandate "may be devastating" and the loss of unvaccinated employees it will produce "may force the cessation of some hospital services and possibly the closure of some departments, all of which will reduce the amount and quality of healthcare services offered to our patients." Ex. J ¶5; Ex. I ¶7 (noting likely loss of 20 or 30 employees leading to "devastating results" to patient care); Ex. H ¶5 (noting Utah healthcare worker shortage at crisis level); Ex. O¶5-9.

State officials confirm the damage to patient wellbeing caused by the Mandate. The Director of the Utah State Hospital and Utah Developmental Center similarly confirmed that "Utah already has a serious direct care shortage in both its State Hospital and State Developmental center that is jeopardizing client and staff safety and care." Ex. G ¶11. "[T]he number of vacant staff positions" at those facilities "has roughly doubled from September 2020 to September 2021," jumping "from 74 to 141" at the State Hospital and "from 50 to 109" at the State Development Center. *Id.* ¶12. "These entities cannot afford to lose any additional staff," *id.* ¶13, but "[i]mplementation of a vaccine mandate without a weekly testing option will likely cause resignations of staff members," and "even a few resignations will exacerbate an understaffing problem at already exists," *id.* ¶15; *see also* Ex. N ¶4-5. The CFO of the Alabama Department of Public Health (ADPH) estimates that "roughly 40% of our covered unvaccinated employees will resign" if the Mandate is implemented, which "jeopardizes the ability of ADPH ... to perform its home-health services to a particularly vulnerable population." Ex. B ¶¶12-13; *see also* Ex. D ¶¶9-11; Ex. E ¶¶12-18. Patient wellbeing is not served by preventing the hiring of qualified healthcare workers—a fact CMS would have known had it bothered to make its required consultations.

Second, the Secretary failed to consider or arbitrarily rejected obvious alternatives to a Vaccine Mandate. The Secretary rejected daily or weekly testing. 86 Fed. Reg. at 61614 ("We have reviewed scientific evidence on testing and found that vaccination is a more effective infection control measure."). That conclusion is facially deficient: it fails to identify the "evidence" supporting this decision, or to explain how such evidence relates to the goal of protecting workers or patients in a healthcare setting. It also contradicts existing evidence in the States. Since July 2021, employees at the Utah State Hospital and Utah State Developmental Center have required to be vaccinated *or* take a weekly COVD-19 test; 14% of employees at the Hospital (119 employees) and 30% of employees at the Developmental Center (164 employees) take the test each week, Ex. G ¶¶7-9, and that alternative

approach has created no apparent harm to patients or staff. That's just one bit of evidence confirming: there is no evidence that vaccination is the *only* acceptable way to protect workers and patients in a healthcare setting. CMS's careful wording reveals as much; its goal here is "effective infection control," 86 Fed. Reg. at 61614, not protection in any particular environment. The rejection of natural immunity as a basis for exemption is equally dismissive and unsupported. *See id.* For example, a highly reported study from Israel involving review of 74,000 cases of infection concluded that a person with natural immunity is 27 times less likely to be reinfected that a vaccinated person. *See* Ex. L ¶¶29-35; Ex. P ¶¶47-53. Other studies support this conclusion. *Id.* (collecting sources).

Third, CMS fails to adequately explain its departure from its—and the Administration's—prior positions. As recounted above, President Biden consistently refused to impose a vaccine mandate throughout the height of the pandemic. And CMS also considered and rejected vaccine mandates and even mandatory vaccine provision. *See, e.g.*, 86 Fed. Reg. 44774, 45380 (Aug. 13, 2021) ("We again note that this measure does not require HCP to receive a COVID–19 vaccine and it does not require HCP to report their vaccination status."); 86 Fed. Reg. 26306, 26314 (May 13, 2021) ("We believe it would be overly burdensome to mandate that each LTC facility educate and offer the COVID–19 vaccine to all individuals who enter the facility."). Apart from briefly acknowledging that it has "not previously required any vaccinations," 86 Fed. Reg. at 61568, CMS offers nothing beyond conclusory statements for departing from this past position, *State v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) (""Stating that a factor was considered ... is not a substitute for considering it.""). Because "agencies must typically provide a 'detailed explanation' for contradicting a prior policy," CMS's failure to do so imbues the IFC with the "hallmarks of unlawful agency actions." *also BST Holdings*, No. 21-60845, at 16-17.

Fourth, the IFC's rationale is flagrantly pretextual. As recounted above, the President has stated several times that the CMS Vaccine Mandate is part of a broader program aimed at increasing

vaccination rates. The IFC, however, eschews this rationale and tries (unsuccessfully) to shoehorn the Mandate into the Social Security Act's statutory factors. The presence of such blatant pretext is enough to render the CMS Vaccine Mandate arbitrary and capricious. *New York*, 139 S. Ct. at 2575-76. What's more, the Administration's shifting rationales across all vaccine mandates demonstrate pretext. For example, the OSHA ETS declares that vaccines are necessary to protect worker safety. But that rationale that would not suffice under the Social Security Act, so CMS contrived a new rationale—patient safety—to shoehorn the Mandate into the Social Security Act. Accepting CMS's description of the Vaccine Mandate would require this Court to "'exhibit a naiveté from which ordinary citizens are free.'" *Id.*; *see also BST Holdings*, No. 21-60845, at 16-17 ("OSHA's reversal here strains credulity, as does its pretextual basis.").

Fifth, the CMS rule ignores Plaintiff States' overwhelming reliance interests in their Medicare and Medicaid systems. Specifically, the IFC ignores: (1) the Plaintiff States' reliance interests in their healthcare providers continuing to operate under existing rules without facing this new Mandate that threatens to significantly harm the States' citizens, particularly those in rural communities; (2) healthcare providers' similar reliance interests in staffing their facilities under the existing rules without facing this new Mandate that threatens their workforce, the services they provide, and their very existence, Ex. F ¶¶4-5; and (3) healthcare workers' reliance interests, especially the interests of minority workers in rural communities, in selecting a job and building a career under the existing rules. The IFC is arbitrary and capricious because it ignores those reliance interests. *See DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913-14 (2020).

Sixth, the Vaccine Mandate's scope is arbitrary and capricious. The Mandate reaches many categories of healthcare facilities, such as psychiatric residential treatment facilities for individual under 21 years of age, *see* 86 Fed. Reg. at 61576, that are not related to CMS's asserted interest in protecting elderly and infirm patients from the transmission of COVID-19. Indeed, CMS recognizes that "risk

of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person." *Id.* at 61610 n.247. Beyond that, the Mandate applies to "any individual that . . . has the potential to have contact with anyone at the site of care." *Id.* at 61571 (emphasis added). This includes "staff that primarily provide services remotely via telework" but "occasionally encounter fellow staff . . . who will themselves enter a health care facility." *Id.* at 61570. And the Mandate also covers a contracted "crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks." *Id.* at 61571. The Mandate's vast reach is far removed from the purported purpose of protecting patient safety.

For each of those independently sufficient reasons, the OMB Rule is arbitrary and capricious.

D. The Contractor Vaccine Mandate Violates the Spending Clause, Tenth Amendment, and Anti-Commandeering Doctrine.

"[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Nothing in federal law gave States clear notice that a vaccine mandate would be a condition of accepting federal Medicare or Medicaid funds. And for the reasons discussed above, the Vaccine Mandate goes far beyond the federal interest in patient health and wellbeing. Thus, the CMS Vaccine Mandate violates the Spending Clause because it is not necessary to preventing the spread of COVID-19. *See NFIB*, 567 U.S. at 579. Additionally, because noncompliance with the Vaccine Mandate threatens a substantial portion of Plaintiff States' budgets, it violates the Spending Clause by leaving the States with no choice but to acquiesce. *See id.* at 581-82 ("The threatened loss of over 10 percent of a State's overall budget, in contrast, is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion.").

The Mandate also violates the Tenth Amendment's Anti-Commandeering Doctrine. The Tenth Amendment and the Constitution's structure deprive Congress of "the power to issue direct

orders to the governments of the States," *Murphy v. NCAA*, 138 S. Ct. 1461, 1476 (2018), and forbid the federal government to commandeer State officers "into administering federal law," *Printz v. United States*, 521 U.S. 898, 928 (1997). Just like the now-stayed OSHA ETS—which "commandeers U.S. employers to compel millions of employees to receive a COVID-19 vaccine or bear the burden of weekly testing," *BTS Holdings*, No. 21-60845, at 17—the Vaccine Mandate violates this doctrine by requiring Plaintiff States' state-run hospitals covered by the Mandate to either fire their unvaccinated employees or lose all Medicare and Medicaid funding. The Vaccine Mandate also commandeers the States because it forces State surveyors to enforce the Mandate by verifying healthcare provider compliance. *E.g.*, Ex. B ¶18; Ex. M. This "dragoons" States into enforcing federal policy by threatening Plaintiff States' Medicare and Medicaid funds in violation of the Anti-Commandeering Doctrine.

II. PLAINTIFF STATES WILL SUFFER IRREPARABLE HARM WITHOUT AN INJUNCTION.

"To show irreparable injury if threatened action is not enjoined, it is not necessary to demonstrate that harm is inevitable and irreparable." *Humana, Inc. v. Avram A. Jacobson, M.D., P.A.*, 804 F.2d 1390, 1394 (5th Cir. 1986). Instead, plaintiffs need only show that they are "likely to suffer irreparable harm in the absence of preliminary relief." *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018). The evidence here confirms that the Vaccine Mandate will cause the Plaintiff States to suffer a barrage of irreparable harms.

First, the Mandate causes irreparable economic injuries. "[C]omplying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Texas v. E.P.A.*, 829 F.3d 405, 433 (5th Cir. 2016) (internal quotation marks omitted). As the Fifth Circuit recently explained, that is "because federal agencies generally enjoy sovereign immunity for any monetary damages," so an injured party has no redress. *Wages & White Lion Invs., L.L.C. v. F.D.A.*, 2021 WL 4955257, at *8 (5th Cir. Oct. 26, 2021); *see also Texas v. United States*, 809 F.3d 134, 186 (5th Cir. 2015) (financial injury from federal government irreparable). Unless enjoined, the Mandate will

force the Plaintiff States' own facilities to dedicate considerable resources in the coming weeks to implementing arduous tracking and documentation processes. *See* Ex. L ¶¶12, 17-20. It forces them to fire their workers who do not wish to submit to vaccination no later than December 6. As a natural and foreseeable result, the Plaintiff States' healthcare facilities will reduce services and lose revenue. *E.g.*, Ex. C ¶¶11-12. And because Defendants enjoy sovereign immunity, "[n]o mechanism here exists for the [Plaintiffs] to recover the compliance costs they will incur if the Final Rule is invalidated." *Texas v. E.P.A.*, 829 F.3d at 434. The resulting unemployment will also likely cause the Plaintiff States to lose tax revenue and spend more on public benefits. *BST Holdings*, No. 21-60845, at 18-19.

Second, the Mandate injures the States' sovereign interests by purporting to preempt their laws. An injury to a State's sovereign interest is "necessarily" irreparable. *See, e.g.*, *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013). A State's interest in "in not being pressured to change its law" is sufficiently "related to its sovereignty" for these purposes. *Texas v. United States*, 787 F.3d 733, 752 n.38 (5th Cir. 2015); *see also Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017) ("[T]he State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws."). Here, Plaintiff States will have to change their own laws and policies to comply with the Mandate. The Mandate purports to directly preempt Montana's H.B. 702, which prohibits discrimination based on vaccination status; Indiana's H.B. 1405, which prohibits government entities from requiring anyone—including employees—to show proof of vaccination; and Utah's H.B. 308, which prohibits state agencies from conditioning employment on vaccination. *See* 86 Fed. Reg. at 61613. The Mandate also purports to compel the States' own providers to implement new policies and the States' own surveyors to enforce new rules in the place of those that they would implement and enforce absent the Mandate. Ex. M ¶7; *BST Holdings*, No. 21-60845, at 19.

Third, the Mandate economically injures the Plaintiff States' citizens and thereby injures the States' *parens patriae* interests. A State may assert those injuries of its citizen in which it has a "quasi-

sovereign interest." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982). A State has a paradigmatic sovereign interest in "the health and well-being—both physical and economic—of its residents in general." *Id.* A State also has a sovereign interest in "assuring that the benefits of the federal system are not denied to its general population." *Id.* at 608. As extensively recounted in Section I.C and the cited declarations, the Mandate irreparably injures those interests because it will naturally and foreseeably cause healthcare employees to lose their jobs, thereby exacerbating the healthcare labor shortage, causing further unemployment, and leading the States' citizens to lose access to adequate medical care—or to lose access to federal benefits altogether. *See Texas v. E.P.A.*, 829 F.3d at 434 (irreparable injury to State in the prospect of loss of basic infrastructure); *BST Holdings*, No. 21-60845, at 18-19; Ex. K ¶¶7-9; Ex. F ¶¶4-5; Ex. G ¶¶10-15; Ex. A ¶¶3-5. It will also force the States' healthcare-employee citizens to forfeit control over their private medical choices, personal information, and bodily autonomy to their employers and to the federal government. Ex. L ¶¶17-20; Ex. P ¶¶3, 21-22.

Fourth, the States will suffer the irreparable injury of the deprivation of their statutorily guaranteed procedural rights. A plaintiff has a "cognizable injury if it has been deprived of a procedural right to protects its concrete interests." *Texas v. Equal Emp't Opportunity Comm'n*, 933 F.3d 433, 447 (5th Cir. 2019) (quotations and alterations omitted). And "[a] violation of the APA's notice-and-comment requirements is one example of a deprivation of a procedural right." *Id.* Here, the States were denied multiple procedural rights, including the APA's and CRA's notice-and-comment requirements, to protect their wide range of concrete interests in avoiding the Mandate. If the procedurally defective Mandate remains in effect, they will have no remedy.

Of course, to avoid those injuries, the States and their facilities could forfeit their Medicare and Medicaid funds. But doing so would cause them to lose billions of dollars and would catalyze a public-health crisis. Those consequences would irreparably injure the State and its citizens. *State of Fla.*

v. Weinberger, 492 F.2d 488, 492 (5th Cir. 1974) ("The calamitous prospect of such a loss of funding, even for a short period, to the state and to the disadvantaged citizens for whom it stands parens patriae is so grave as to suffice for such hardship as may be required.").

III. AN INJUNCTION WOULD NOT HARM DEFENDANTS OR DISSERVE THE PUBLIC INTEREST.

Finally, the public interest and balance of equities weigh in favor of granting a preliminary injunction. Simply put, Defendants "have no legitimate interest in the implementation of [the] unlawful" Vaccine Mandate. *Texas*, 2021 WL 723856, at *49. Instead, "the public is served when the law is followed." *Id.* at *51 (quoting *Daniels Health Scis., L.L.C. v. Vascular Health Scis., L.L.C.*, 710 F.3d 579, 585 (5th Cir. 2013)); *see also League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) ("There is generally no public interest in the perpetuation of unlawful agency action."). The public has an overriding interest in ensuring that vast regulatory programs are implemented lawfully, in compliance with the constitutional separation of powers and APA. *Cf. United States v. Baylor Univ. Med. Ctr.*, 711 F.2d 38, 40 (5th Cir. 1983) (stay warranted where "[t]he interest of the Medicaid and Medicare recipients would be seriously compromised should [a medical center] be put to the Hobson's choice" of continuing to litigate or "decid[ing] to forfeit its Medicaid and Medicare funds"). And while Plaintiff States would be irreparably harmed by the implementation of the Mandate, the only harm to the Defendants from an injunction would be to wait for an actual grant of authority from Congress. Accordingly, the public interest and balance of harms weigh heavily in Plaintiff States' favor.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiff States' Motion for a Preliminary Injunction.

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Respectfully submitted,

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